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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,535	06/03/2005	Eric Thomas McAdams	595552000100	4773

20872 7590 08/17/2010
MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

EXAMINER

DANEGA, RENEE A

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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08/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,535	Applicant(s) MCADAMS, ERIC THOMAS	
	Examiner Renee Danega	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/16/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-40,46-48,50,53-56,59 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34-40,46-48,50,53-56,59 and 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 31, 34-36, 39-40 and 46-48, 50, 53-56, 59 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US 6963772) in view of Pearlman (US 6308097) and Masuo (US 20030176808), and Kenan et al. (US 6788966).

- Regarding claims 31, 34-37, 39-40, 47-48, 50, 54-56, 59, 62, 64 Bloom teaches a system and method for monitoring changes in a skin wound over time comprising a wound dressing (40) including a two dimensional rectangular array of at least 25 test electrodes (38) for application to the surface of the wound (4), circuit means comprising switching device and analyzer for passing an electrical alternating current between each selected test electrode and a further electrode electrically coupled to the test electrodes for measuring an impedance of the tissue underlying each test electrode (78), and a display means (92) capable of presenting a visual map indicating the size and shape of the lesion. Bloom teaches the circuit comprising a first test electrode for providing a current source (4)

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integrated in the two-dimensional array of test electrodes, a second test electrode (10) for completing a current loop with the first electrode, and a third test electrode applied to tissue adjacent the first electrode (38's) (Figures 2D and 4) Bloom doesn't expressly teach presenting a visual map indicating the size and shape of the wound nor an analyzer calculating the voltage difference being measured while passing electrical alternating current between a selected test electrode and at least one further electrode. However, Pearlman teaches a device that employs current through multiple electrodes on hydrogel at the skin surface in order to map a lesion (abstract) (Figures 7B, 14-15) column 9, lines 39-52) (column 4, lines 47-65). Pearlman further teaches the analyzer (Figure 17A) measures the voltage difference by passing alternating current between a selected test electrode and the reference electrode and determining the difference in order to reduce the baseline impedance contributed to the local impedance and improve the image (column 19, lines 57-66). Additionally, Masuo provides a skin impedance measuring device in which the reference electrode measures the difference between two current carrying electrodes to determine tissue abnormalities [0031] (Figure 3). It would have been obvious in view of Pearlman to use impedance and a measured voltage difference in order to create an image and display of abnormalities. Additionally, Masuo provides a skin impedance measuring device in which the reference electrode measures the difference between

two current carrying electrodes to determine tissue abnormalities.

Pearlman doesn't expressly teach the device to be used for skin lesions.

However, Kanan teaches that skin impedance measurements can be used to identify skin lesions. It would have been obvious in view of Kanan to use the system of Bloom to monitor skin lesions and track changes.

- Regarding claim 48, Bloom teaches measuring impedance over a plurality of frequencies but doesn't expressly teach a range. However, Pearlman teaches measuring tissue anomalies by taking impedance measurements over a range of 1mHz to 100 kHz (column 21, lines 14-28). It would have been obvious in view of Pearlman to take impedance measurements in this range in Bloom to detect tissue anomalies.
- Regarding claims 46 and 53, Bloom teaches the test electrodes arranged on a flexible backing of insulating material with the electrodes covered with a conductive gel inherently creating high resistance between the electrodes relative to the resistance to the underlying tissue (column 11, lines 5-21).
- Regarding claims 63 and 65, Bloom teaches at least one reference electrode is a dedicated electrode on the flexible backing of insulating material (Figure 2C).

3. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claims 31 above, and further in view of Cudahy et al. (US 5184620).

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- Regarding claim 38, Bloom teaches the leads (4) to be disposed on the flexible backing of insulating material with the electrodes (38) (Figure 4), but doesn't expressly teach the leads to be covered with an insulating material. However, Cudahy teaches the electrodes to be insulated by the pad from other conductors (column 6, lines 17-20). It would have been obvious in view of Cudahy to provide insulation over the leads in Bloom as well as the electrodes to prevent conductance between the wires.

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

5. Upon further review of the Pearlman reference, it appears that the reference teaches incorporating an additional electrode and analyzer for calculating a difference between two current-carrying electrodes. Furthermore, the incorporation of Masuo teaches a system carrying out impedance differential measurements in this manner in order to analyze tissue near the skin.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736